

DIESSE DIAGNOSTICA SENESE SpA  
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## QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgM

Code 91011

LOT.NO 336



2025-06



2024-03

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	675	2025-07	1
PF30107	006380	CONJUGATE	236	2025-06	1
PF93900/CMM	C4870	NEGATIVE CONTROL	818	2025-09	1
PF92012	006310	POSITIVE CONTROL	217	2025-09	1
PF91811	006400	CUT OFF CONTROL	221	2025-09	1
PF91611	007330	ANTIGEN ( 3 ml )	194	2026-09	6
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	387	2025-09	1

### CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.067	< 0,6 Cut Off
CUT OFF CONTROL	0.311	≥ 0.200
POSITIVE CONTROL	1.764	> 1,5 Cut Off
CV %	6%	≤ 15%

Evaluatin of the method according to the package inset in the attached document  
This batch has been manufactured and checked according to quality requirements.  
Hereby, it is released to distribution.

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 25.06.2024

### WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.

IO 09- 002-V



CODE 91011

CODE 91171

## QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT CYTOMEGALOVIRUS IgM  
LOT. 336  
DATE OF TEST 13/06/2024

### METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.041	
	CV%	4%	< 20%
2nd PLATE	OD 450 nm	2.155	
	CV%	13%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.851	
	CV%	8%	< 15%
2. BULK CONTROL date: 10/06/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.330	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 14/06/2024			
A) Blank	OD 450 nm	0.051	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.067	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.311	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.764	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	6	
	OD 450 nm	0.362	
	CV%	6%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 14/06/2024

Signed:

Released: Q.C. Manager